IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 13-1524-SLR

DEFENDANT PAR'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO TAKEDA'S AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Par Pharmaceutical, Inc. ("Par Pharmaceutical") and Par Pharmaceutical Companies, Inc. ("Par Companies"), (collectively, "Par") by and through their attorneys, for their Answer to the Complaint of Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda" or "Plaintiff"), hereby declare as follows:

NATURE OF THE ACTION

1. Par admits that the Complaint purports to be an action for patent infringement arising under the Food and Drug and Patent Laws of the United States, U.S.C. Titles 21 and 35 respectively, arising from Par Pharmaceutical's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to sell commercially a generic version of the drug product COLCRYS® (colchicine, USP) prior to the expiration of United States Patent Nos. 7,906,519; 7,935,731; 8,093,298; 7,964,648; 8,093,297; 7,619,004; 7,601,758; 7,820,681; 7,915,269; 7,964,647; 7,981,938; 8,093,296; 8,097,655; 8,415,395; 8,415,396; 8,440,721; and 8,440,722. Par denies that Par

Companies submitted an ANDA to the FDA seeking approval to sell commercially a generic version of the drug product COLCRYS®. Par denies the remaining allegations of Paragraph 1.

THE PARTIES

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Takeda. Par is also without knowledge and information sufficient to form a belief as to whether Takeda owns the entire right, title, and interest in each patent asserted in this action. Par thus denies all allegations of Paragraph 2.

3. Par avers that Par Companies is a Delaware corporation and is in the business of, *inter alia*, making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Par admits that Par Companies has its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

4. Par avers that Par Pharmaceutical is a Delaware corporation and is in the business of, *inter alia*, making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Par admits that Par Pharmaceutical has its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977

5. Par admits that Par Pharmaceutical is a wholly-owned subsidiary of Par Companies. Par denies the remaining allegations of Paragraph 5.

6. Par denies the allegations of Paragraph 6.

JURISDICTION AND VENUE

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par admits the Complaint purports to be for patent infringement under 35 U.S.C. § 271. Par denies all remaining allegations of paragraph 7.

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par states that for Counts I –V of this action only, Par

Pharmaceutical does not dispute that this Court has jurisdiction over the subject matter of this action with respect to Par Pharmaceutical. Par denies the remaining allegations of Paragraph 8.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Pharmaceutical is a Delaware corporation, and regularly does business in this district by selling generic pharmaceutical products. Par admits that Par Pharmaceutical has previously consented to personal jurisdiction in this District, and has asserted counterclaims in other actions initiated in this District. Par Pharmaceutical further admits that for the limited purposes of this action only, Par Pharmaceutical does not contest personal jurisdiction of this Court. Par denies the remaining allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Companies is a Delaware corporation, that it regularly does business in this district by selling generic pharmaceutical products. Par admits that Par Companies has previously consented to personal jurisdiction in this District and has asserted counterclaims in other actions initiated in this jurisdiction. Par denies the remaining allegations of Paragraph 10.

11. Paragraph 11 states a legal conclusion to which no response is required. To the extent a response is required, for the limited purpose of this action only, Par Pharmaceutical does not contest venue in this judicial district. Par denies that venue is proper in this District as to Par Companies.

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

12. Par admits that COLCRYS® is primarily used to prevent and treat gout flares, and that COLCRYS® is the only oral single-active-ingredient colchicine product approved by the FDA for the treatment and prevention of gout flares. Par is without knowledge or

information sufficient to form a belief as to the truth or sufficiency of the remaining allegations of Paragraph 12, and thus denies the remaining allegations of Paragraph 12.

13. Par admits that COLCRYS® is also used to treat Familial Mediterranean Fever ("FMF"), and that COLCRYS® is the only single-active-ingredient oral colchicine product approved by the FDA to treat FMF. Par is without knowledge or information sufficient to form a belief as to the truth or sufficiency of the remaining allegations of Paragraph 13, and thus denies the remaining allegations of Paragraph 13.

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the FDA approved COLCRYS® for marketing in the United States.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that the Orange Book lists that COLCRYS® has Orphan Drug exclusivity which expires July 29, 2016.

16. Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 16.

17. Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Par is without knowledge and information sufficient to form a belief as to whether Takeda is the lawful owner of all right, title, and interest in the following patents, including the right to sue and to recover for infringement thereof, and whether said patents contain one or more claims covering methods of use of COLCRYS®. Par thus denies the allegations of Paragraph 17.

A. Par admits a document which appears to be the '519 patent is attached to the complaint as Exhibit A; that the '519 patent, on its face, is titled "METHODS FOR

CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," states the date of issue as March 15, 2011, and names Matthew Davis as the inventor. Par denies that the '519 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(A).

B. Par admits that a document which appears to be the '731 patent is attached to the Complaint as Exhibit B; that the '731 patent, on its face, is titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and names Matthew Davis as the inventor. Par denies that the '731 patent was duly and legally issued on May 11, 2011. Par denies any remaining allegations of Paragraph 17(B).

C. Par admits that a document which appears to be the '298 patent is attached to the Complaint as Exhibit C; that the '298 patent, on its face, is titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," and that it states the date of issue as January 10, 2012, and names Matthew Davis as the inventor. Par denies that the '298 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(C).

D. Par admits that a document which appears to be the '648 patent is attached to the Complaint as Exhibit D; that the '648 patent, on its face, is titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," states the date of issue as June 21, 2011, and names Matthew Davis as the inventor. Par denies that the '648 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(D).

E. Par admits that a document which appears to be the '297 patent is attached to the Complaint as Exhibit E; that the '297 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND A SECOND ACTIVE AGENT," states the date of issue as January 10, 2012, and names Matthew Davis as the inventor. Par denies that the '297 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(E).

F. Par admits that a document which appears to be the '004 patent is attached to the Complaint as Exhibit F; that the '004 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," states the date of issue as November 17, 2009, and names Matthew Davis as the inventor. Par denies that the '004 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(F).

G. Par admits that a document which appears to be the '758 patent is attached to the Complaint as Exhibit G; that the '758 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS IN THE TREATMENT OF GOUT FLARES," states the date of issue as October 13, 2009, and names Matthew Davis as the inventor. Par denies that the '758 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(G).

H. Par admits that a document which appears to be the '681 patent is attached to the Complaint as Exhibit H; that the '681 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," states the date of issue as October 26, 2010, and names Matthew Davis as the

inventor. Par denies that the '681 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(H).

I. Par admits that a document which appears to be the '269 patent is attached to the Complaint as Exhibit I; that the '269 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND A SECOND ACTIVE AGENT," states the date of issue as March 29, 2011, and names Matthew Davis as the inventor. Par denies that the '269 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(I).

J. Par admits that a document which appears to be the '647 patent is attached to the Complaint as Exhibit J; that the '647 patent, on its face, is entitled "COLCHICINE COMPOSITIONS AND METHODS," states the date of issue as June 21, 2011, and names Matthew Davis as the inventor. Par denies that the '647 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(J).

K. Par admits that a document which appears to be the '938 patent is attached to the Complaint as Exhibit K; that the '938 patent, on its face, is entitled "COLCHICINE COMPOSITIONS AND METHODS," states the date of issue as July 19, 2011, and names Matthew Davis as the inventor. Par denies that the '938 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(K).

L. Par admits that a document which appears to be the '296 patent is attached to the Complaint as Exhibit L; that the '296 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND MACROLIDE ANTIBIOTICS," states the date of issue as January 10, 2012, and names Matthew Davis as the

inventor. Par denies that the '296 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(L).

M. Par admits that a document which appears to be the '655 patent is attached to the Complaint as Exhibit M; that the '655 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND MACROLIDE ANTIBIOTICS," states the date of issue as January 17, 2012, and names Matthew Davis as the inventor. Par denies that the '655 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(M).

N. Par admits that a document which appears to be the '395 patent is attached to the Complaint as Exhibit N; that the '395 patent, on its face, is entitled "COLCHICINE COMPOSITIONS AND METHODS," states the date of issue as April 9, 2013, and names Matthew Davis and Hengsheng Feng as the inventors. Par denies that the '395 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(N).

O. Par admits that a document which appears to be the '396 patent is attached to the Complaint as Exhibit O; that the '396 patent, on its face, is entitled "COLCHICINE COMPOSITIONS AND METHODS," states the date of issue as April 9, 2013, and names Matthew Davis and Hengsheng Feng as the inventors. Par denies that the '396 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(O).

P. Par admits that a document which appears to be the '721 patent is attached to the Complaint as Exhibit P; that the '721 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND A SECOND ACTIVE AGENT," states the date of issue as May 14, 2013, and names Matthew Davis as the inventor.

Par denies that the '721 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(P).

Q. Par admits that a document which appears to be the '722 patent is attached to the Complaint as Exhibit Q; that the '722 patent, on its face, is entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHCINE AND A SECOND ACTIVE AGENT," states the date of issue as May 14, 2013, and names Matthew Davis as the inventor. Par denies that the '722 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 17(Q).

18. No response is required to the defined term of Paragraph 18. To the extent a response is required, Par admits that the '519. '731, '298, '648, and '297 patents may be called the "FMF Patents," though the '297 and '648 patents contain claims that do not recite methods of treating FMF, or recite methods of treating both FMF and gout.

19. No response is required to the defined term of Paragraph 19. To the extent a response is required, Par admits that the '004, '758, '681, '269, '647, '648, '938, '296, '655, '395, '396, '721, and '722 patents may be called the "Gout Patents."

20. No response is required to the defined term of Paragraph 20. To the extent a response is required, Par admits that all of the above listed patents may be referred to as the "COLCRYS® Patents."

21. Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the COLCRYS® Patents are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"), and that the Orange Book is maintained by the FDA. Par denies the remaining allegations of Paragraph 21.

THE GOUT AND FMF MARKETS IN THE UNITED STATES

22. Par is without sufficient information to admit or deny the allegations of Paragraph 22, and thus denies the allegations of Paragraph 22.

23. Par is without sufficient information to admit or deny the allegations of Paragraph 23, and thus denies the allegations of Paragraph 23.

24. Par denies the allegations of Paragraph 24.

PHYSICIAN AND PHARMACY PRESCRIBING PRACTICES

25. Par is without sufficient information to admit or deny the allegations of Paragraph 25 and therefore denies the allegations of Paragraph 25.

26. Paragraph 26 calls for a legal conclusion to which no response is required. To the extent a response is required, Par avers that physicians do not always control whether a pharmacist fills a prescription with a brand drug or with any particular generic version, although they may elect to do so. Par is without sufficient information to admit or deny the remaining allegations of Paragraph 26 and thus denies the allegations of Paragraph 26.

27. Par is without sufficient information to admit or deny the allegations of Paragraph 27, and thus denies the allegations of Paragraph 27.

PAR'S ACTIONS GIVING RISE TO THIS SUIT

28. Par admits that in December 2011 Par Pharmaceutical submitted ANDA No. 20-3976 to the FDA seeking approval to engage in the commercial manufacture and sale of 0.6 mg oral colchicine tablets. Par states that the term "Par's Proposed Product" is confusing to the extent that it alleges that Par Companies submitted ANDA No. 20-3976 to the FDA seeking approval to engage in the commercial manufacture and sale of 0.6 mg oral colchicine tablets, and will instead refer to said product as "Par Pharmaceutical's Proposed Product" throughout this Answer. Par denies all remaining allegations of Paragraph 28.

29. Paragraph 29 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that Par Pharmaceutical sent AR Holding Company, Inc. a letter as required by 21 U.S.C. §355(j)(B)(ii)(II), dated February 21, 2012 and signed by a representative of Par Pharmaceutical, informing AR Holding Company, Inc. of Par Pharmaceutical's supplemental amendment of its Paragraph IV Certification in ANDA No. 20-3976 to include U.S. Patent Nos. 8,093,296; 8,093,297; and 8,097,655. Par further avers that this supplemental amendment was made in response to AR Holding Company, Inc. listing U.S. Patent Nos. 8,093,296; 8,093,297; and 8,097,655 in the Orange Book. Par avers that it asserted in that letter that the '648 and '297 patents are invalid or would not be infringed with respect to the treatment and prevention of gout flares and that Par was not seeking FDA approval for the treatment of FMF indication based on a "carve out" pursuant to §355(j)(2)(A)(viii).

30. Paragraph 30 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that Par Pharmaceutical sent AR Holding Company, Inc. a letter as required by 21 U.S.C. §355(j)(B)(ii)(I), dated March 13, 2012 and signed by a representative of Par Pharmaceutical, informing AR Holding Company, Inc. of Par Pharmaceutical's filing of a Paragraph IV Certification in ANDA No. 20-3976. Par avers that it asserted in that letter that the '648 and '297 patents are invalid or would not be infringed with respect to the treatment and prevention of gout flares and that Par was not seeking FDA approval for the treatment of FMF indication based on a "carve out" pursuant to §355(j)(2)(A)(viii). Par denies the remaining allegations of Paragraph 30.

31. Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that AR Holding Company, Inc. filed a lawsuit against Par Pharmaceutical in this District alleging, *inter alia*, that pursuant to 35 U.S.C. § 271, Par

Pharmaceutical had committed an act of infringement by submitting an ANDA with a Paragraph IV Certification seeking approval to engage in the commercial use, manufacture, sale, offer to sell, or importation of Par Pharmaceutical's Proposed Product prior to the expiration of the '648 and '297 Patents. Par denies the remaining allegations of Paragraph 31.

32. Par avers that ANDA No. 20-3976 does not presently seek approval for the purpose of manufacturing and selling Par Pharmaceutical's Proposed Product for the treatment and prevention of gout flares. Par denies the remaining allegations of Paragraph 32.

33. Paragraph 33 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Pharmaceutical sent Takeda notice of the Paragraph IV Certifications with respect to the '519, '731, and '298 patents. Par further avers that it previously notified AR Holding Company, Inc. of its Paragraph IV Certifications as to at least the '648 patent and '297 patents, which certifications have not been amended since originally made. Par states that the term "Par's Third Paragraph IV Notice Letter" is confusing to the extent that it alleges that Par Companies sent said Notice Letter to Takeda, and will instead refer to said notice letter as "Par Pharmaceutical's Supplemental Paragraph IV Notice Letter" throughout this answer. Par avers that Par Pharmaceutical's Supplemental Paragraph IV Notice Letter alleges that the '519, '731, and '298 Patents are invalid and/or will not be infringed by commercial use or sale of Par Pharmaceutical's Proposed Product. Par denies the remaining allegations of Paragraph 33.

34. Par avers that counsel for Par Pharmaceutical informed counsel for Takeda that (a) Par Pharmaceutical intended to remove dosing instructions or safety information for the treatment or prevention of gout flares from its proposed labeling (by telephone on July 16, 2013); and that (b) Par Pharmaceutical's proposed labeling does not include dosing instructions or

safety information for the treatment or prevention of gout flares (by e-mail on July 19, 2013). Par avers that Par Pharmaceutical's Supplemental Notice Letter informed Takeda that its proposed labeling does not cover the treatment of gout flares or prophylaxis of gout flares. Par denies the remaining allegations of Paragraph 34.

35. Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Pharmaceutical submitted a label amendment to the FDA stating that Par Pharmaceutical sought to carve out the gout indications from its package insert. Par denies all remaining allegations of Paragraph 35.

36. Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that the FDA approved product label for COLCRYS® contains instructions for using COLCRYS® in treating and preventing gout flares and also contains instructions for dose modification of COLCRYS® in the event of concomitant therapy with another substance. Par denies the remaining allegations of Paragraph 36.

37. Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that the FDA approved product label for COLCRYS® contains instructions for using COLCRYS® in treating FMF and also contains instructions for dose modification of COLCRYS® in the event of concomitant therapy with another substance. Par denies the remaining allegations of Paragraph 37.

38. Paragraph 38 states a legal conclusion to which no response is required. To the extent a response is required, Par states that the statutes and regulations cited speak for themselves and denies any factual allegations of Paragraph 38 and any other allegations of Paragraph 38 to the extent they are inconsistent with the statutes or regulations cited.

39. Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 39.

40. Paragraph 40 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 40.

41. Par denies the allegations of Paragraph 41.

42. Par denies the allegations of Paragraph 42.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Pharmaceutical continues to seek approval of ANDA No. 203976 from the FDA. Par denies the remaining allegations of Paragraph 43.

44. Par denies the allegations of Paragraph 44.

45. Par denies the allegations of Paragraph 45.

46. Par avers that Takeda commenced a civil action with respect to the '519, '731, '298, '648, and '297 patents within 45 days of receiving Par's Third Paragraph IV Notice Letter. Par denies the remaining allegation of Paragraph 46.

COUNT I
(Infringement of the '519 Patent)[1]

47. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 46 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 46.

48. Paragraph 48 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 48

49. Par admits that Par Pharmaceutical submitted to the FDA ANDA No. 20-3976 seeking to obtain approval to manufacture and sell Par Pharmaceutical's Proposed Product prior

[1] Headings are reprinted here with the same language as used in Plaintiff's Complaint simply for ease of reference, and do not constitute an admission.

to the stated expiration of the '519 patent. Par denies that by submitting ANDA No. 20-3976, Par Pharmaceutical committed an act of infringement under 35 U.S.C. §271(e)(2)(A), and Par denies the remaining allegations of Paragraph 49.

50. Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 50.

51. Par denies the allegations of Paragraph 51.

52. Paragraph 52 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 52.

53. Paragraph 53 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 53.

COUNT II
(Infringement of the '731 Patent)

54. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 53 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 53.

55. Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 55.

56. Par admits that Par Pharmaceutical submitted to the FDA ANDA No. 20-3976 seeking to obtain approval to manufacture and sell Par Pharmaceutical's Proposed Product prior to the stated expiration of the '731 patent. Par denies that by submitting ANDA No. 20-3976, Par Pharmaceutical committed an act of infringement under 35 U.S.C. §271(e)(2)(A), and Par denies the remaining allegations of Paragraph 56.

57. Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 57.

58. Par denies the allegations of Paragraph 58.

59. Paragraph 59 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 59.

60. Paragraph 60 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 60.

COUNT III
(Infringement of the '298 Patent)

61. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 60 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 60.

62. Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 62.

63. Par admits that Par Pharmaceutical submitted to the FDA ANDA No. 20-3976 seeking to obtain approval to manufacture and sell Par Pharmaceutical's Proposed Product prior to the stated expiration of the '298 patent. Par denies that by submitting ANDA No. 20-3976, Par Pharmaceutical committed an act of infringement under 35 U.S.C. §271(e)(2)(A), and Par denies the remaining allegations of Paragraph 63.

64. Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 64.

65. Par denies the allegations of Paragraph 65.

66. Paragraph 66 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 66.

67. Paragraph 67 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 67.

COUNT IV
(Infringement of the '648 Patent)

68. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 67 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 67.

69. Paragraph 69 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 69.

70. Par admits that Par Pharmaceutical submitted to the FDA ANDA No. 20-3976 seeking to obtain approval to manufacture and sell Par Pharmaceutical's Proposed Product prior to the stated expiration of the '648 patent. Par denies that by submitting ANDA No. 20-3976, Par Pharmaceutical committed an act of infringement under 35 U.S.C. §271(e)(2)(A), and Par denies the remaining allegations of Paragraph 70.

71. Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 71.

72. Paragraph 72 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '648 patent, but Par denies the remaining allegations of Paragraph 72.

73. Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 73.

74. Par denies the allegations of Paragraph 74.

75. Paragraph 75 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 75.

76. Paragraph 76 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 76.

COUNT V
(Infringement of the '297 Patent)

77. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 76 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 76.

78. Paragraph 78 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 78.

79. Par admits that Par Pharmaceutical submitted to the FDA ANDA No. 20-3976 seeking to obtain approval to manufacture and sell Par Pharmaceutical's Proposed Product prior to the stated expiration of the '297 patent. Par denies that by submitting ANDA No. 20-3976, Par Pharmaceutical committed an act of infringement under 35 U.S.C. §271(e)(2)(A), and Par denies the remaining allegations of Paragraph 79.

80. Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 80.

81. Paragraph 81 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '297 patent, but Par denies the remaining allegations of Paragraph 81.

82. Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 82.

83. Par denies the allegations of Paragraph 83.

84. Paragraph 84 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 84.

85. Paragraph 85 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 85.

COUNT VI
(Infringement of the '004 Patent)

86. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 85 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 85.

87. Paragraph 87 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '004 patent, but Par denies the remaining allegations of Paragraph 87.

88. Paragraph 88 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 88.

89. Paragraph 89 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 89.

90. Paragraph 90 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 90.

COUNT VII
(Infringement of the '758 Patent)

91. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 90 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 90.

92. Paragraph 92 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '758 patent, but Par denies the remaining allegations of Paragraph 92.

93. Paragraph 93 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 93.

94. Par denies the allegations of Paragraph 94.

95. Paragraph 95 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 95.

96. Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 96.

COUNT VIII
(Infringement of the '681 Patent)

97. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 96 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 96.

98. Paragraph 98 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '681 patent, but Par denies the remaining allegations of Paragraph 98.

99. Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 99.

100. Par denies the allegations of Paragraph 100.

101. Paragraph 101 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 101.

102. Paragraph 102 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 102.

COUNT IX
(Infringement of the '269 Patent)

103. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 102 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 102.

104. Paragraph 104 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '269 patent, but Par denies the remaining allegations of Paragraph 104.

105. Paragraph 105 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 105.

106. Par denies the allegations of Paragraph 106.

107. Paragraph 107 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 107.

108. Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 108.

COUNT X
(Infringement of the '647 Patent)

109. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 108 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 108.

110. Paragraph 110 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '647 patent, but Par denies the remaining allegations of Paragraph 110.

111. Paragraph 111 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 111.

112. Par denies the allegations of Paragraph 112.

113. Paragraph 113 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 113.

114. Paragraph 114 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 114.

COUNT XI
(Infringement of the '938 Patent)

115. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 114 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 114.

116. Paragraph 116 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '938 patent, but Par denies the remaining allegations of Paragraph 116.

117. Paragraph 117 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 117.

118. Par denies the allegations of Paragraph 118.

119. Paragraph 119 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 119.

120. Paragraph 120 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 120.

COUNT XII
(Infringement of the '296 Patent)

121. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 120 the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 120.

122. Paragraph 122 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '296 patent, but Par denies the remaining allegations of Paragraph 122.

123. Paragraph 123 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 123.

124. Par denies the allegations of Paragraph 124.

125. Paragraph 125 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 125.

126. Paragraph 126 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 126.

COUNT XIII
(Infringement of the '655 Patent)

127. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 126 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 126.

128. Paragraph 128 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '655 patent, but Par denies the remaining allegations of Paragraph 128.

129. Paragraph 129 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 129.

130. Par denies the allegations of Paragraph 130.

131. Paragraph 131 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 131.

132. Paragraph 132 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 132.

COUNT XIV
(Infringement of the '395 Patent)

133. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 132 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 132.

134. Paragraph 134 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '395 patent, but Par denies the remaining allegations of Paragraph 134.

135. Paragraph 135 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 135.

136. Par denies the allegations of Paragraph 136.

137. Paragraph 137 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 137.

138. Paragraph 138 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 138.

COUNT XV
(Infringement of the '396 Patent)

139. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 138 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 138.

140. Paragraph 140 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '396 patent, but Par denies the remaining allegations of Paragraph 140.

141. Paragraph 141 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 141.

142. Paragraph 142 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 142.

143. Paragraph 143 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 143.

COUNT XVI
(Infringement of the '721 Patent)

144. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 143 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 143.

145. Paragraph 145 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '721 patent, but Par denies the remaining allegations of Paragraph 145.

146. Paragraph 146 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 146.

147. Par denies the allegations of Paragraph 147.

148. Paragraph 148 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 148.

149. Paragraph 149 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 149.

COUNT XVII
(Infringement of the '722 Patent)

150. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 149 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 149.

151. Paragraph 151 states a legal conclusion to which no response is required. To the extent a response is required, Par Pharmaceutical admits that it has knowledge of the '722 patent, but Par denies the remaining allegations of Paragraph 151.

152. Paragraph 152 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 152.

153. Par denies the allegations of Paragraph 153.

154. Paragraph 154 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 154.

155. Paragraph 155 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 155.

EXCEPTIONAL CASE

156. Par admits that Par Pharmaceutical was aware of the Patents before Par Pharmaceutical submitted a label amendment for ANDA No. 203976. Par denies the remaining allegations of Paragraph 156.

157. Par denies the allegations of Paragraph 157.

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF

Par denies that Takeda is entitled to the relief it seeks in Paragraphs (A)–(H) or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Takeda's allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein.

FIRST SEPARATE DEFENSE
(Invalidity of the '519 Patent)

158. The claims of the '519 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SECOND SEPARATE DEFENSE
(Invalidity of the '731 Patent)

159. The claims of the '731 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

THIRD SEPARATE DEFENSE
(Invalidity of the '298 Patent)

160. The claims of the '298 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

FOURTH SEPARATE DEFENSE
(Invalidity of the '648 Patent)

161. The claims of the '648 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

FIFTH SEPARATE DEFENSE
(Invalidity of the '297 Patent)

162. The claims of the '297 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SIXTH SEPARATE DEFENSE
(Invalidity of the '004 Patent)

163. The claims of the '004 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SEVENTH SEPARATE DEFENSE
(Invalidity of the '758 Patent)

164. The claims of the '758 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

EIGHTH SEPARATE DEFENSE
(Invalidity of the '681 Patent)

165. The claims of the '681 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

NINTH SEPARATE DEFENSE
(Invalidity of the '269 Patent)

166. The claims of the '269 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

TENTH SEPARATE DEFENSE
(Invalidity of the '647 Patent)

167. The claims of the '647 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

ELEVENTH SEPARATE DEFENSE
(Invalidity of the '938 Patent)

168. The claims of the '938 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

TWELFTH SEPARATE DEFENSE
(Invalidity of the '296 Patent)

169. The claims of the '296 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

THIRTEENTH SEPARATE DEFENSE
(Invalidity of the '655 Patent)

170. The claims of the '655 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

FOURTEENTH SEPARATE DEFENSE
(Invalidity of the '395 Patent)

171. The claims of the '395 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

FIFTEENTH SEPARATE DEFENSE
(Invalidity of the '396 Patent)

172. The claims of the '396 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SIXTEENTH SEPARATE DEFENSE
(Invalidity of the '721 Patent)

173. The claims of the '721 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

SEVENTEENTH SEPARATE DEFENSE
(Invalidity of the '722 Patent)

174. The claims of the '722 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

EIGHTEENTH SEPARATE DEFENSE
(Non-Infringement of the '519 Patent)

175. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '519 patent.

176. The manufacture, use, sale, offer for sale, and/or importation into the United

States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '519 patent under the doctrine of equivalents.

NINTEENTH SEPARATE DEFENSE
(Non-Infringement of the '731 Patent)

177. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '731 patent.

178. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '731 patent under the doctrine of equivalents.

TWENTIETH SEPARATE DEFENSE
(Non-Infringement of the '298 Patent)

179. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '298 patent.

180. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '298 patent under the doctrine of equivalents.

TWENTY-FIRST SEPARATE DEFENSE
(Non-Infringement of the '648 Patent)

181. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '648 patent.

182. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '648 patent under the doctrine of equivalents.

TWENTY-SECOND SEPARATE DEFENSE
(Non-Infringement of the '297 Patent)

183. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '297 patent.

184. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '297 patent under the doctrine of equivalents.

TWENTY-THIRD SEPARATE DEFENSE
(Non-Infringement of the '004 Patent)

185. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '004 patent.

186. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '004 patent under the doctrine of equivalents.

TWENTY-FOURTH SEPARATE DEFENSE
(Non-Infringement of the '758 Patent)

187. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '758 patent.

188. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '758 patent under the doctrine of equivalents.

TWENTY-FIFTH SEPARATE DEFENSE
(Non-Infringement of the '681 Patent)

189. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '681 patent.

190. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '681 patent under the doctrine of equivalents.

TWENTY-SIXTH SEPARATE DEFENSE
(Non-Infringement of the '269 Patent)

191. The manufacture, use, sale, offer for sale, and/or importation into the United

States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '269 patent.

192. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '269 patent under the doctrine of equivalents.

TWENTY-SEVENTH SEPARATE DEFENSE
(Non-Infringement of the '647 Patent)

193. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '647 patent.

194. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '647 patent under the doctrine of equivalents.

TWENTY-EIGHTH SEPARATE DEFENSE
(Non-Infringement of the '938 Patent)

195. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '938 patent.

196. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '938 patent under the doctrine of equivalents.

TWENTY-NINTH SEPARATE DEFENSE
(Non-Infringement of the '296 Patent)

197. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '296 patent.

198. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '296 patent under the doctrine of equivalents.

THIRTIETH SEPARATE DEFENSE
(Non-Infringement of the '655 Patent)

199. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '655 patent.

200. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '655 patent under the doctrine of equivalents.

THIRTY-FIRST SEPARATE DEFENSE
(Non-Infringement of the '395 Patent)

201. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '395 patent.

202. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the

infringement of any valid or enforceable claim of the '395 patent under the doctrine of equivalents.

THIRTY-SECOND SEPARATE DEFENSE
(Non-Infringement of the '396 Patent)

203. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '396 patent.

204. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '396 patent under the doctrine of equivalents.

THIRTY-THIRD SEPARATE DEFENSE
(Non-Infringement of the '721 Patent)

205. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '721 patent.

206. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '721 patent under the doctrine of equivalents.

THIRTY-FOURTH SEPARATE DEFENSE
(Non-Infringement of the '722 Patent)

207. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the literal infringement of any valid or enforceable claim of the '722 patent.

208. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not contribute to the infringement of any valid or enforceable claim of the '722 patent under the doctrine of equivalents.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Counterclaimants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par"), assert the following counterclaims against Plaintiff/Counterdefendant Takeda Pharmaceuticals, U.S.A., for declaratory judgment that the sale and/or offer for sale of the 0.6 mg colchicine tablets described in Par's ANDA No. 203976 ("Par's ANDA Product") will not contribute to the infringement of U.S. Patent Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,093,297 ("the '297 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively, "the Gout Patents"); will not infringe U.S. Patent Nos. 7,906,519 ("the '519 patent");7,935,731 ("the '731 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); and 8,097,298 ("the '298 patent") (collectively, the "FMF Patents"); and/or that the Gout Patents and FMF Patents are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

THE PARTIES

1. Counterclaimant Par Pharmaceutical, Inc. is a Delaware corporation with its

principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

2. Counterclaimant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

3. On information and belief, and based on its allegations, Counterclaim-Defendant/Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

NATURE OF THE ACTION

4. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief— a declaration that the sale, offer-for-sale, distribution, or importation into the United States of the 0.6 mg colchicine tablets described in Par Pharmaceutical, Inc.'s Abbreviated New Drug Application ("ANDA") No. 203976 ("Par's ANDA Product") will not contribute to the infringement of the Gout Patents, and/or that the Gout Patents are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Par and Takeda, arising under the patent laws of the United States, 35 U.S.C. §1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

6. This Court has personal jurisdiction over Takeda based on, *inter alia*, its filing of this lawsuit in this jurisdiction.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

8. The '004 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as November 17, 2009.

9. The '758 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares" and states its date of issue as October 13, 2009.

10. The '681 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as October 26, 2010.

11. The '269 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as March 29, 2011.

12. The '647 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as June 21, 2011.

13. The '648 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as June 21, 2011.

14. The '938 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as July 19, 2011.

15. The '296 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as January 10, 2012.

16. The '297 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as January 10, 2012.

17. The '655 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics" and states its date of issue as January 17, 2012.

18. The '395 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as April 9, 2013.

19. The '396 patent, on its face, is titled "Colchicine Compositions and Methods" and states its date of issue as April 9, 2013.

20. The '721 patent, on its face, is titled "Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as May 14, 2013.

21. The '722 patent, on its face, is titled Methods for Concomitant Administration of Colchicine and a Second Active Agent" and states its date of issue as May 14, 2013.

22. The earliest effective filing date to which the '758, '655, '004, '296, '731, and '298 patents claim priority on their faces is October 15, 2008.

23. The earliest effective filing date to which the '681, '648, '269, '297, '721, and '722 patents claim priority on their faces is January 14, 2009.

24. The earliest effective filing date to which the '647, '938, '395, and '396 patents claim priority on their faces is October 5, 2007.

25. On information and belief, and based on Takeda's allegations, Takeda is the owner of all right, title, and interest in the Gout Patents.

26. On information and belief, and based on Takeda's allegations, Takeda is the holder of New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353 for colchicine, sold in the United States as COLCRYS®.

27. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 22-351 on July 30, 2009.

28. On information and belief, the FDA approved NDA No. 22-352 on July 29, 2009.

29. On information and belief, the FDA approved NDA No. 22-353 on October 16,

2009.

PAR'S ANDA PRODUCT

30. On September 4, 2014, Takeda served Par with an Amended Complaint alleging that Par will contribute to the infringement of the Gout Patents by selling, offering for sale, distributing, or importing Par's ANDA Product upon approval of ANDA No. 20-3976.

31. On July 19, 2013, Par submitted a label amendment to the FDA such that the proposed label originally submitted with ANDA No. 20-3976 would be amended for the purpose of limiting FDA approval of its ANDA Product to the treatment of FMF, and that pursuant to 21 U.S.C. §355(j)(2)(A)(viii), Par sought to carve out from the FDA-approved COLCRYS® label information regarding the treatment and prevention of gout flares, including all dosing instructions for the treatment and prevention of gout flares.

32. Based upon the label amendment to the FDA described in Paragraph 30, the proposed labeling for Par's ANDA Product will not include any dosage or administration instructions directing a patient to use its product to treat or prevent gout flares, nor any instructions for dose modification in the event of concomitant therapy of gout with another substance.

33. Based upon the label amendment to the FDA described in Paragraph 30, the proposed labeling for Par's ANDA Product will include dosage and administration instructions directing a patient to use Par's ANDA Product for treatment of FMF.

TAKEDA'S FDA APPROVED PRODUCT LABEL FOR COLCRYS®

34. Upon information and belief, a true and correct copy of Takeda's most recent FDA-approved product label for COLCRYS® is attached to these Counterclaims as Exhibit 1.

35. The "INDICATIONS AND USAGE" section of Takeda's FDA approved product label for COLCRYS® lists that "COLCRYS is indicated for prophylaxis of gout flares."

COLCRYS® Prescribing Information, Exhibit 1, at 3.

36. The "INDICATIONS AND USAGE" section of Takeda's FDA approved product label for COLCRYS® also lists that "COLCRYS tablets are indicated for treatment of acute gout flares when taken at the first sign of flare." *Id.*

37. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® also states that the "recommended dose of COLCRYS for treatment of a gout flare is 1.2 mg (2 tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later." *Id.*

38. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® states that the "recommended dosage of COLCRYS for prophylaxis of gout flares for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose for prophylaxis of gout flares is 1.2 mg/day." *Id.*

39. The "DOSAGE AND ADMINISTRATION" section also states that

> Co-administration of COLCRYS with drugs known to inhibit CYP3A4 and/or P-glycoprotein (P-gp) increases the risk of colchicine-induced toxic effects (Table 1). If patients are taking or have recently completed treatment with drugs listed in Table 1 within the prior 14 days, the dose adjustments are as shown on the table below…

Table 1. COLCRYS Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡ (pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

P-gp Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Cyclosporine Ranolazine	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other P-gp inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

*For magnitude of effect on colchicine plasma concentrations *[see Pharmacokinetics (12.3)]*

†Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with strong CYP3A4 or P-gp inhibitors *[see Contraindications (4)]*

‡When used in combination with Ritonavir, see dosing recommendations for strong CYP3A4 inhibitors *[see Contraindications (4)]*

Table 1. COLCRYS Dose Adjustment for Coadministration with Interacting Drugs if no Alternative Available*

Strong CYP3A4 Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Atazanavir Clarithromycin Darunavir/ Ritonavir‡ Indinavir Itraconazole Ketoconazole Lopinavir/ Ritonavir‡ Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Tipranavir/ Ritonavir‡	Significant increase in colchicine plasma levels*; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Amprenavir‡ Aprepitant Diltiazem Erythromycin Fluconazole Fosamprenavir‡ (pro-drug of Amprenavir) Grapefruit juice Verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	0.6 mg twice a day 0.6 mg once a day	0.3 mg twice a day or 0.6 mg once a day 0.3 mg once a day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

P-gp Inhibitors†

Drug	Noted or Anticipated Outcome	Gout Flares				FMF	
		Prophylaxis of Gout Flares		Treatment of Gout Flares			
		Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose	Original Intended Dosage	Adjusted Dose
Cyclosporine Ranolazine	Significant increase in colchicine plasma levels*: fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other P-gp inhibitors.	0.6 mg twice a day 0.6 mg once a day	0.3 mg once a day 0.3 mg once every other day	1.2 mg (2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	0.6 mg (1 tablet) x 1 dose. Dose to be repeated no earlier than 3 days.	Maximum daily dose of 1.2 – 2.4 mg	Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

*For magnitude of effect on colchicine plasma concentrations *[see Pharmacokinetics (12.3)]*

†Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with strong CYP3A4 or P-gp inhibitors *[see Contraindications (4)]*

‡When used in combination with Ritonavir, see dosing recommendations for strong CYP3A4 inhibitors *[see Contraindications (4)]*

Id. at 4–5 (internal cross-references omitted).

40. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® thus instructs doctors to administer or patients to take 0.6 mg of colchicine once or twice a day (i.e., up to 1.2 mg of colchicine a day in the form of two 0.6 mg colchicine tablets) for prophylaxis of gout flares if the patient is not taking or has not recently completed treatment with CYP3A4 inhibitors such as ketoconazole, clarithromycin, ritonavir, erythromycin, or verapamil. *Id.*

41. The "DOSAGE AND ADMINISTRATION" section of Takeda's FDA approved product label for COLCRYS® instructs doctors to administer or patients to take 1.2 mg (2 tablets) of colchicine at the first sign of the gout flare followed by 0.6 mg (1 tablet) of colchicine one hour later for treatment of gout flares only if the patient is not taking or has not recently completed treatment with CYP3A4 inhibitors such as ketoconazole, clarithromycin, ritonavir, erythromycin, or verapamil. *Id.*

42. The "CLINICAL STUDIES" section of Takeda's FDA approved product label for COLCRYS® states that

> The evidence for the efficacy of colchicine in patients with chronic gout is derived from the published literature. Two randomized clinical trials assessed the efficacy of colchicine 0.6 mg twice a day for the prophylaxis of gout flares in patients with gout initiating treatment with urate lowering therapy. In both trials, treatment with colchicine decreased the frequency of gout flares.

Id. at 19.

43. Upon information and belief, the "evidence for the efficacy of colchicine in patients with chronic gout" referenced in Takeda's FDA approved product label for COLCRYS® includes at least two pieces of published literature: "Prophylactic Colchicine Therapy of Intercritical Gout: A Placebo-Controlled Study in Probenecid-Treated Patients" by Paulus, et al. (Arthritis & Rheumatism, 17:5, 609, 1974) ("The Paulus Study") and "Colchicine

for Prophylaxis of Acute Flares when Initiating Allopurinol for Chronic Gouty Arthritis" by Borstad, Bryant et al. (J. Rheum. 31:12, 2429, 2004) ("The Borstad Study"). *See* Exhibit 2, United States Food and Drug Administration Summary Review Letter for NDA 22-353 (Colcrys (colchicine)) at 10-13 (Oct. 16, 2009).

44. The Paulus Study was published in 1974, more than one year prior to October 5, 2007.

45. The Borstad Study was published in 2004, more than one year prior to October 5, 2007.

46. Upon information and belief, Takeda advertises that COLCRYS "helps prevent gout flares[.]" *See* Exhibit 3, "About COLCRYS (colchicine, USP)" (available at www.colcrys.com/about.aspx; last accessed September 12, 2014).

47. Upon information and belief, Takeda advertises that "based on current treatment guidelines from the American College of Rheumatology, your doctor may prescribe COLCRYS (colchicine, USP) along with uric acid-lowering medicine. For preventing flares, when uric acid-lowering medication is taken along with COLCRYS, 1 or 2 tablets (up to 1.2 mg daily) is recommended daily. *See* Exhibit 4, "Taking COLCRYS (colchicine, USP) Medication for Gout" (available at www.colcrys.com/taking-colcrys.aspx; last accessed September 12, 2014).

48. Upon information and belief, administering 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares is a substantial use of 0.6 mg colchicine tablets.

49. Upon information and belief, administering 0.6 mg a day of colchicine in the form of one 0.6 mg colchicine tablet for the prophylaxis of gout flares is a substantial use of 0.6 mg colchicine tablets.

COUNTERCLAIM COUNT I
(Non-Infringement of the '758 Patent)

50. Par incorporates by reference Paragraphs 1 through 49 of its Counterclaims as if fully set forth herein.

51. The '758 patent has eleven claims in total.

52. Claims 1 and 10 of the '758 are the only independent claims of the '758 patent.

53. Claims 2–9 of the '758 patent depend, either directly or indirectly, from claim 1.

54. Claim 11 of the '758 patent depends from claim 10.

55. Claim 1 of the '758 patent recites the following:

> 1. A method of using colchicine to treat a gout flare in a human patient who is receiving concomitant administration of clarithromycin or erythromycin, said method comprising:
>
> determining a first colchicine dosage amount adapted for oral administration to the patient to treat a gout flare in the absence of concomitant administration of clarithromycin or erythromycin,
>
> determining a second colchicine dosage amount that is about a two thirds reduction of the first colchicine dosage amount,
>
> orally administering the second colchicine dosage amount to the patient who is experiencing a gout flare and is concomitantly receiving administration of clarithromycin or erythromycin,
>
> wherein concomitant administration of clarithromycin or erythromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount, and not repeating colchicine administration for at least three days.

56. Claim 10 of the '758 patent recites the following:

> 10. A method of using colchicine to treat a gout flare in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin or erythromycin, said method comprising:
>
> administering a reduced colchicine dosage amount to the patient to treat gout flares, wherein the reduced colchicine dosage amount is about 50% to about 75% of a manufacturer's recommended

colchicine dosage amount in the absence of concomitant clarithromycin or erythromycin administration, and

not repeating colchicine administration for at least three days,

wherein concomitant administration of clarithromycin or erythromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

57. Physicians can and will prescribe Par's ANDA Product without concomitant administration of clarithromycin or erythromycin.

58. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin or erythromycin.

59. Par will not contribute to the infringement of any claim of the '758 patent.

60. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '758 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

61. Par is entitled to a judicial declaration that Par's ANDA Product will not contribute to the infringement of the '758 patent.

COUNTERCLAIM COUNT II
(Non-Infringement of the '004 Patent)

62. Par incorporates by reference Paragraphs 1 through 61 of its Counterclaims as if fully set forth herein.

63. The '004 patent has eight claims in total.

64. Claims 1 and 5 of the '004 are the only independent claims of the '004 patent.

65. Claims 2–4 and 8 of the '004 patent depend, either directly or indirectly, from claim 1.

66. Claims 6 and 7 of the '004 patent depend from claim 10.

67. Claim 1 of the '004 patent recites the following:

> 1. A method of using colchicine for prophylactic treatment of gout flares in a human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> orally administering a second colchicine daily dosage amount for prophylactic treatment of gout flares to the human gout patient who is concomitantly receiving administration of clarithromycin, wherein the second colchicine daily dosage amount is a 75% reduction of a first colchicine daily dosage amount suitable for daily oral administration for the prophylactic treatment of gout flares in the absence of concomitant administration of clarithromycin, wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount, and
>
> wherein the first colchicine daily dosage amount is 1.2 mg administered as two 0.6 mg doses per day, and the second colchicine daily dosage amount is 0.3 mg per day, or wherein the first colchicine daily dosage amount is 0.6 mg per day and the second colchicine daily dosage amount is 0.15 mg per day administered as 0.3 mg every other day, or wherein the first colchicine daily dosage amount is 0.6 mg per day and the second colchicine daily dosage amount is 0.15 mg per day.

68. Claim 5 of the '004 patent recites the following:

> 5. A method of using colchicine for prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> administering a reduced colchicine daily dosage amount to the patient for prophylactic treatment of gout flares, wherein the reduced colchicine daily dosage amount is 75% of a manufacturers' recommended colchicine daily dosage amount for the prophylactic treatment of gout flares in the absence of concomitant clarithromycin administration, wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

69. Physicians can and will prescribe Par's ANDA Product without concomitant

administration of clarithromycin.

70. Claim 1 of the '004 patent sets forth a substantial use that will not infringe the '004 patent, in that it describes "a first colchicine daily dosage amount suitable for daily oral administration for the prophylactic treatment of gout flares in the absence of concomitant administration of clarithromycin" which is "1.2 mg administered as two 0.6 mg doses per day[.]"

71. Physicians can and will prescribe, *inter alia*, Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

72. Par will not contribute to the infringement of any claim of the '004 patent.

73. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '004 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

74. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '004 patent is warranted.

COUNTERCLAIM COUNT III
(Non-Infringement of the '681 Patent)

75. Par incorporates by reference Paragraphs 1 through 74 of its Counterclaims as if fully set forth herein.

76. The '681 patent has four claims in total.

77. Claim 1 of the '681 patent is the only independent claim of the '681 patent.

78. Claims 2–4 of the '681 patent depend, either directly or indirectly, from claim 1.

79. Claim 1 of the '681 patent recites the following:

> 1. A method of treating a patient in need of treatment for the prophylaxis of gout flares with colchicine, comprising

> orally administering to the patient in need of treatment for the prophylaxis of gout flares, an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of 200 mg per day of ritonavir;
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of 0.6 mg twice per day or 0.6 mg once per day, which is an amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

80. If, as Takeda has alleged, physicians will prescribe Par's ANDA Product for gout consistent with their previous prescription practices for COLCRYS®, physicians can and will prescribe Par's ANDA Product without concomitant administration of ritonavir.

81. Claim 1 of the '681 patent sets forth a substantial non-infringing use, in that it describes administering 0.6 mg twice per day or 0.6 mg once per day as an amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

82. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

83. Par will not contribute to the infringement of any claim of the '681 patent.

84. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '681 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

85. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '681 patent is warranted.

COUNTERCLAIM COUNT IV
(Non-Infringement of the '269 Patent)

86. Par incorporates by reference Paragraphs 1 through 85 of its Counterclaims as if

fully set forth herein.

87. The '269 patent has one claim.

88. Claim 1 of the '269 patent recites the following:

> 1. A method of treating a patient in need of treatment for gout flares with colchicine, comprising
>
> orally administering to the patient in need of treatment for gout flares, an adjusted daily dosage amount of colchicine wherein the patient is receiving concomitant administration of 200 mg per day of ritonavir,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of an intended daily dosage amount in the absence of concomitant ritonavir, wherein the intended daily dosage amount in the absence of concomitant ritonavir is 1.2 mg at the first sign of flare, followed by 0.6 mg one hour later, dose to be repeated no earlier than 3 days.

89. Physicians can and will prescribe Par's ANDA Product without concomitant administration of ritonavir.

90. Claim 1 of the '269 patent sets forth a substantial non-infringing use, in that it describes an intended daily dosage amount of colchicine in the absence of concomitant ritonavir which is 1.2 mg colchicine at the first sign of flare, followed by 0.6 mg colchicine one hour later, dose to be repeated no earlier than 3 days.

91. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

92. Par will not contribute to the infringement of any claim of the '269 patent.

93. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '269 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory

judgment.

94. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '269 patent is warranted.

COUNTERCLAIM COUNT V
(Non-Infringement of the '647 Patent)

95. Par incorporates by reference Paragraphs 1 through 94 of its Counterclaims as if fully set forth herein.

96. The '647 patent has one claim.

97. Claim 1 of the '647 patent recites the following:

> 1. A method of treating a patient having an acute gouty arthritis attack with colchicine consisting of
>
> administering 1.2 mg oral colchicine to a human patient having an acute gouty arthritis attack at the onset of the acute gouty arthritis attack, followed by 0.6 mg oral colchicine one hour later.

98. Par's ANDA Product is not especially adapted for infringement of the '647 patent because Par's ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

99. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient in need thereof.

100. Par will not contribute to the infringement of any claim of the '647 patent.

101. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '647 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

102. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '647 patent is warranted.

COUNTERCLAIM COUNT VI
(Non-Infringement of the '648 Patent)

103. Par incorporates by reference Paragraphs 1 through 102 of its Counterclaims as if fully set forth herein.

104. The '648 patent has eight claims.

105. Claim 1 of the '648 patent is the only independent claim in the '648 patent.

106. Claims 2-8 of the '648 patent depend, either directly or indirectly, from claim 1.

107. Claim 1 of the '648 patent recites the following:

> 1. A method of treating a patient with colchicine, comprising
>
> orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of ketoconazole,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of an intended daily dosage amount of colchicine,
>
> and wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant ketoconazole.

108. Physicians can and will prescribe Par's ANDA Product without concomitant administration of ketoconazole.

109. If, as Takeda has alleged, physicians will prescribe Par's ANDA Product for gout consistent with their previous prescription practices for COLCRYS®, physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ketoconazole.

110. Par will not contribute to the infringement of any claim of the '648 patent.

111. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce

infringement of any valid or enforceable claim of the '648 patent.

112. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '648 patent under the doctrine of equivalents.

113. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '648 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

114. A judicial declaration that Par's ANDA Product will not infringe the '648 patent is warranted.

COUNTERCLAIM COUNT VII
(Non-Infringement of the '938 Patent)

115. Par incorporates by reference Paragraphs 1 through 114 of its Counterclaims as if fully set forth herein.

116. The '938 patent has only one claim.

117. Claim 1 of the '938 patent recites the following:

> 1. A method of treating a gout flare with colchicine in a patient undergoing colchicine prophylactic treatment of gout flares, consisting of
>
> Administering to a patient having a gout flare while undergoing prophylactic treatment of gout flares
>
> 1.2 mgA oral colchicine at the onset of the acute gout flare, followed by 0.6 mgA oral colchicine about one hour later; and
>
> After waiting 12 hours, continuing prophylactic treatment consisting of 0.6 mgA or 1.2 mgA oral colchicine daily.

118. Par's ANDA Product is not especially adapted for infringement of the '938 patent

because Par's ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

119. Claim 1 of the '938 patent sets forth a substantial non-infringing use, in that it describes prophylactic treatment of gout flares with colchicine consisting of 0.6 mgA or 1.2 mgA oral colchicine daily.

120. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient.

121. Par will not contribute to the infringement of any claim of the '938 patent.

122. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '938 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

123. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '295 patent is warranted.

COUNTERCLAIM COUNT VIII
(Non-Infringement of the '296 Patent)

124. Par incorporates by reference Paragraphs 1 through 123 of its Counterclaims as if fully set forth herein.

125. The '296 patent has three claims.

126. Claim 1 of the '296 patent is the only independent claim in the '296 patent.

127. Claims 2-3 of the '296 patent depend, either directly or indirectly, from claim 1.

128. Claim 1 of the '296 patent recites the following:

> 1. A method of using colchicine to treat a gout flare in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:

> orally administering a reduced colchicine dosage amount to the patient to treat gout flares, wherein the reduced colchicine dosage amount is about a 50% to about a 75% reduction of a colchicine dosage amount adapted for oral administration to the gout patient to treat gout flares in the absence of concomitant administration of clarithromycin, and
>
> not repeating colchicine administration for at least three days,
>
> wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the reduced colchicine dosage amount.

129. Physicians can and will prescribe Par's ANDA Product without concomitant administration of clarithromycin.

130. Claim 2 of the '296 patent sets forth a substantial non-infringing use, in that it describes a colchicine dosage amount adapted for oral administration to the gout patient to treat gout flares in the absence of concomitant administration of clarithromycin which is 1.2 mg at the first sign of a flare followed by 0.6 mg one hour later.

131. Physicians can and will prescribe Par's ANDA Products at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

132. Par will not contribute to the infringement of any claim of the '296 patent.

133. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '296 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

134. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '296 patent is warranted.

COUNTERCLAIM COUNT IX
(Non-Infringement of the '297 Patent)

135. Par incorporates by reference Paragraphs 1 through 134 of its Counterclaims as if fully set forth herein.

136. The '297 patent has nine claims.

137. Claim 1 of the '297 patent is the only independent claim in the '297 patent.

138. Claims 2-9 of the '297 patent depend, either directly or indirectly, from claim 1.

139. Claim 1 of the '297 patent recites the following:

> 1. A method of treating a patient in need of treatment for gout or familial Mediterranean fever with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of colchicine to the patient who is receiving concomitant administration of a recommended daily dosage of ritonavir,
>
> wherein the adjusted daily dosage amount of colchicine is 25% to 50% of a daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir.

140. Physicians can and will prescribe Par's ANDA Product without concomitant administration of a recommended daily dosage of ritonavir.

141. Claim 2 of the '297 patent sets forth a substantial non-infringing use, in that it describes "treating with colchicine… for the prophylaxis of gout flares, and wherein the daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant ritonavir is 0.6 mg twice daily or 0.6 mg once daily."

142. Physicians can and will prescribe Par's ANDA Products at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of ritonavir.

143. Par will not contribute to the infringement of any claim of the '297 patent.

144. The manufacture, use, sale, offer for sale, and/or importation into the United

States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '297 patent.

145. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe or induce infringement of any valid or enforceable claim of the '297 patent under the doctrine of equivalents.

146. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '297 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

147. A judicial declaration that Par's ANDA Product will not infringe the '297 patent is warranted.

COUNTERCLAIM COUNT X
(Non-Infringement of the '655 Patent)

148. Par incorporates by reference Paragraphs 1 through 147 of its Counterclaims as if fully set forth herein.

149. The '655 patent has five claims.

150. Claim 1 of the '655 patent is the only independent claim in the '655 patent.

151. Claims 2-5 of the '655 patent depend, either directly or indirectly, from claim 1.

152. Claim 1 of the '655 patent recites the following:

> 1. A method of using colchicine for the prophylactic treatment of gout flares in an adult human gout patient so as to reduce the occurrence of colchicine toxicity when said patient is receiving concomitant administration of clarithromycin, said method comprising:
>
> orally administering a reduced colchicine daily dosage amount to the patient for prophylactic treatment of gout flares, wherein the

reduced daily colchicine dosage amount is a 75% reduction of a colchicine dosage amount adapted for oral administration to the gout patient for the prophylaxis of gout flares in the absence of concomitant administration of clarithromycin,

wherein concomitant administration of clarithromycin is administration within 1 to 2 days of orally administering the second colchicine dosage amount.

153. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of clarithromycin.

154. Claim 2 of the '655 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes a "colchicine dosage amount adapted for oral administration to a the gout patient for the prophylaxis of gout flares in the absence of concomitant administration of clarithromycin" which "is 0.6 mg twice per day."

155. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of clarithromycin.

156. Par will not contribute to the infringement of any claim of the '655 patent.

157. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '655 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

158. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '655 patent is warranted.

COUNTERCLAIM COUNT XI
(Non-Infringement of the '395 Patent)

159. Par incorporates by reference Paragraphs 1 through 158 of its Counterclaims as if fully set forth herein.

160. The '395 patent has twenty claims.

161. Claims 1 and 13 of the '395 patent are the only independent claims in the '395 patent.

162. Claims 2-12 of the '395 patent depend, either directly or indirectly, from claim 1

163. Claims 14-20 of the '395 patent depend, either directly or indirectly, from claim 13.

164. Claim 1 of the '395 patent recites the following:

> 1. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration;
>
> the method providing lower incidence of an adverse event in a randomized placebo-controlled study compared to a second method of orally administering 4.8 mg oral colchicine over a period of 6 hours.

165. Claim 13 of the '395 patent recites the following:

> 13. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration;
>
> the method characterized by an incidence of a gastrointestinal adverse event that is not significantly different from incidence of the gastrointestinal adverse event characterizing administration of placebo.

166. Par's ANDA Product is not especially adapted for infringement of the '395 patent because Par's ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

167. Claim 1 of the '395 patent sets forth a substantial use that will not infringe the '395 patent, in that it describes "a second method of orally administering 4.8 mg oral colchicine over a period of 6 hours."

168. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient.

169. Par will not contribute to the infringement of any claim of the '395 patent.

170. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '395 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

171. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '395 patent is warranted.

COUNTERCLAIM COUNT XII
(Non-Infringement of the '396 Patent)

172. Par incorporates by reference Paragraphs 1 through 171 of its Counterclaims as if fully set forth herein.

173. The '396 patent has twenty-six claims.

174. Claims 1, 6, 11, and 19 of the '396 patent are the only independent claims in the '396 patent.

175. Claims 2-5 of the '396 patent depend, either directly or indirectly, from claim 1

176. Claims 7-10 of the '396 patent depend, either directly or indirectly, from claim 6.

177. Claims 12-18 of the '396 patent depend, either directly or indirectly, from claim 11.

178. Claims 20-26 of the '396 patent depend, either directly or indirectly, from claim 19.

179. Claim 1 of the '396 patent recites the following:

> 1. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after administering the 1.2 mg colchicine,
>
> the method providing an apparent total body clearance (C L/F) in a range of 2.4 L/hr to 5.3 L/hr.

180. Claim 6 of the '396 patent recites the following:

> 6. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after administering the 1.2 mg colchicine,
>
> the method providing an apparent total volume of distribution (V_{area}/F) in a range of 0.77 L/hr to 1.7 L/hr.

181. Claim 11 of the '396 patent recites the following:

> 11. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration,
>
> the method providing a maximum colchicine blood plasma concentration (C_{max}) in a range of 3.2 to 11.4 ng/mL, and a time after the first administration at which C_{max} is reached (T_{max}) of 1.0 to 2.5 hr.

182. Claim 19 of the '396 patent recites the following:

> 19. A method of treating a patient having a gout flare, the method consisting of:
>
> orally administering 1.2 mg colchicine to a human patient at onset of a gout flare; and then
>
> orally administering 0.6 mg colchicine to the patient about one hour after the first administration,
>
> the method providing a mean maximum colchicine blood plasma concentration (C_{max}) in a range of 3.8 to 8.6 ng/mL and a mean time after the first administration at which C_{max} is reached (T_{max}) in a range of 1.4 to 2.2 hr.

183. Par's ANDA Product is not especially adapted for infringement of the '396 patent because Par's ANDA Product may be taken for, *inter alia*, FMF and prophylaxis of gout flares.

184. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient .

185. Par will not contribute to the infringement of any claim of the '396 patent.

186. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '396 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

187. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '396 patent is warranted.

COUNTERCLAIM COUNT XIII
(Non-Infringement of the '721 Patent)

188. Par incorporates by reference Paragraphs 1 through 187 of its Counterclaims as if fully set forth herein.

189. The '721 patent has four claims.

190. Claim 1 of the '721 patent is the only independent claim in the '721 patent.

191. Claims 2-4 of the '721 patent depend, either directly or indirectly, from claim 1.

192. Claim 1 of the '721 patent recites the following:

> 1. A method of treating a patient in need of treatment for acute gout flares with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of amount of colchicine to the patient who is receiving concomitant administration of verapamil,
>
> wherein the adjusted daily dosage amount of colchicine is 50% to 75% of an intended daily dosage amount of colchicine,
>
> wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant verapamil, wherein the intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil is 1.2 mg at the first sign of flare, followed by 0.6 mg one hour later, and wherein the concomitantly administered dose of verapamil is 240 mg per day.

193. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of verapamil.

194. Claim 1 of the '721 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes an "intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil," which "is 1.2 mg at the first sign of flare, followed by 0.6 mg one hour later[.]"

195. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares who is not receiving concomitant administration of verapamil.

196. Par will not contribute to the infringement of any claim of the '721 patent.

197. A definite and concrete, real and substantial, justiciable controversy exists

between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '721 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

198. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '721 patent is warranted.

COUNTERCLAIM COUNT XIV
(Non-Infringement of the '722 Patent)

199. Par incorporates by reference Paragraphs 1 through 198 of its Counterclaims as if fully set forth herein.

200. The '722 patent has two claims.

201. Claim 1 of the '722 patent is the only independent claim in the '722 patent.

202. Claim 2 of the '722 patent depends from claim 1.

203. Claim 1 of the '722 patent recites the following:

> 1. A method of treating a patient in need of treatment for prophylaxis of gout flares with colchicine, comprising:
>
> orally administering an adjusted daily dosage amount of amount of colchicine to the patient who is receiving concomitant administration of verapamil,
>
> wherein the adjusted daily dosage amount of colchicine is 50% to 75% of an intended daily dosage amount of colchicine,
>
> wherein the intended daily dosage amount of colchicine is a dosage amount suitable for the patient if the patient were not receiving concomitant verapamil, wherein the intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil is 0.6 mg twice daily or 0.6 mg once daily, and wherein the concomitantly administered dose of verapamil is 240 mg per day.

204. Physicians can and will prescribe Par's ANDA Product to patients who are not receiving concomitant administration of verapamil.

205. Claim 1 of the '722 patent sets forth a substantial non-infringing use of 0.6 mg colchicine tablets, in that it describes an "intended daily dosage amount of colchicine suitable for the patient if the patient were not receiving concomitant verapamil," which "is 0.6 mg twice daily or 0.6 mg once daily[.]"

206. Physicians can and will prescribe Par's ANDA Product at a dosage of 1.2 mg a day of colchicine in the form of two 0.6 mg colchicine tablets for the prophylaxis of gout flares to a patient who is not receiving concomitant administration of verapamil.

207. Par will not contribute to the infringement of any claim of the '722 patent.

208. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement by Par's ANDA Product of the '722 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

209. A judicial declaration that Par's ANDA Product will not contribute to the infringement of the '722 patent is warranted.

COUNTERCLAIM COUNT XV
(Non-Infringement of the '519 Patent)

210. Par incorporates by reference Paragraphs 1 through 209 of its Counterclaims as if fully set forth herein.

209. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '519 patent.

210. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce

infringement of, or contribute to the infringement of any valid or enforceable claim of the '519 patent under the doctrine of equivalents.

211. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the '519 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

212. A judicial declaration that Par's ANDA Product will not infringe the '519 patent is warranted.

COUNTERCLAIM COUNT XVI
(Non-Infringement of the '731 Patent)

213. Par incorporates by reference Paragraphs 1 through 213 of its Counterclaims as if fully set forth herein.

211. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '731 patent.

212. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '731 patent under the doctrine of equivalents.

214. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the '731 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

215. A judicial declaration that Par's ANDA Product will not infringe the '731 patent is warranted.

COUNTERCLAIM COUNT XVII
(Non-Infringement of the '298 Patent)

216. Par incorporates by reference Paragraphs 1 through 215 of its Counterclaims as if fully set forth herein.

213. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '298 patent.

214. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par Pharmaceutical's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '298 patent under the doctrine of equivalents.

217. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the alleged infringement of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

218. A judicial declaration that Par's ANDA Product will not infringe the '298 patent is warranted.

COUNTERCLAIM COUNT XIX
(Invalidity of the '758 Patent)

219. Par incorporates by reference Paragraphs 1 through 219 of its Counterclaims as if fully set forth herein.

220. The claims of the '758 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

221. A definite and concrete, real and substantial, justiciable controversy exists

between Par and Takeda concerning the validity of the '758 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

222. A judicial declaration that the '758 patent is invalid is warranted.

COUNTERCLAIM COUNT XX
(Invalidity of the '004 Patent)

223. Par incorporates by reference Paragraphs 1 through 222 of its Counterclaims as if fully set forth herein.

224. The claims of the '004 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

225. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '004 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

226. A judicial declaration that the '004 patent is invalid is warranted.

COUNTERCLAIM COUNT XXI
(Invalidity of the '681 Patent)

227. Par incorporates by reference Paragraphs 1 through 226 of its Counterclaims as if fully set forth herein.

228. The claims of the '681 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

229. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '681 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

230. A judicial declaration that the '681 patent is invalid is warranted.

COUNTERCLAIM COUNT XXII
(Invalidity of the '269 Patent)

231. Par incorporates by reference Paragraphs 1 through 231 of its Counterclaims as if fully set forth herein.

232. The claims of the '269 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

233. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '269 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

234. A judicial declaration that the '269 patent is invalid is warranted.

COUNTERCLAIM COUNT XXIII
(Invalidity of the '647 Patent)

235. Par incorporates by reference Paragraphs 1 through 235 of its Counterclaims as if fully set forth herein.

236. The claims of the '647 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

237. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '647 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

238. A judicial declaration that the '647 patent is invalid is warranted.

COUNTERCLAIM COUNT XXIV
(Invalidity of the '938 Patent)

239. Par incorporates by reference Paragraphs 1 through 238 of its Counterclaims as if

fully set forth herein.

240. The claims of the '938 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

241. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '938 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

242. A judicial declaration that the '938 patent is invalid is warranted.

COUNTERCLAIM COUNT XXV
(Invalidity of the '296 Patent)

243. Par incorporates by reference Paragraphs 1 through 242 of its Counterclaims as if fully set forth herein.

244. The claims of the '296 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

245. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '296 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

246. A judicial declaration that the '296 patent is invalid is warranted.

COUNTERCLAIM COUNT XXVI
(Invalidity of the '655 Patent)

247. Par incorporates by reference Paragraphs 1 through 247 of its Counterclaims as if fully set forth herein.

248. The claims of the '655 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et*

seq.

249. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '655 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

250. A judicial declaration that the '655 patent is invalid is warranted.

COUNTERCLAIM COUNT XXVII
(Invalidity of the '395 Patent)

251. Par incorporates by reference Paragraphs 1 through 250 of its Counterclaims as if fully set forth herein.

252. The claims of the '395 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

253. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '395 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

254. A judicial declaration that the '395 patent is invalid is warranted.

COUNTERCLAIM COUNT XXVIII
(Invalidity of the '396 Patent)

255. Par incorporates by reference Paragraphs 1 through 254 of its Counterclaims as if fully set forth herein.

256. The claims of the '396 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

257. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '396 patent, which is of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment.

258. A judicial declaration that the '396 patent is invalid is warranted.

COUNTERCLAIM COUNT XXIX
(Invalidity of the '721 Patent)

259. Par incorporates by reference Paragraphs 1 through 258 of its Counterclaims as if fully set forth herein.

260. The claims of the '721 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

261. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '721 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

262. A judicial declaration that the '721 patent is invalid is warranted.

COUNTERCLAIM COUNT XXX
(Invalidity of the '722 Patent)

263. Par incorporates by reference Paragraphs 1 through 262 of its Counterclaims as if fully set forth herein.

264. The claims of the '722 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

265. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '722 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

266. A judicial declaration that the '722 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXI
(Invalidity of the '519 Patent)

267. Par incorporates by reference Paragraphs 1 through 266 of its Counterclaims as if fully set forth herein.

268. The claims of the '519 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

269. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '519 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

270. A judicial declaration that the '519 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXII
(Invalidity of the '731 Patent)

271. Par incorporates by reference Paragraphs 1 through 270 of its Counterclaims as if fully set forth herein.

272. The claims of the '731 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

273. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '731 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

274. A judicial declaration that the '731 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXIII
(Invalidity of the '297 Patent)

275. Par incorporates by reference Paragraphs 1 through 271 of its Counterclaims as if

fully set forth herein.

276. The claims of the '297 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

277. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '297 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

278. A judicial declaration that the '297 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXIV
(Invalidity of the '298 Patent)

279. Par incorporates by reference Paragraphs 1 through 278 of its Counterclaims as if fully set forth herein.

280. The claims of the '298 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

281. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

282. A judicial declaration that the '298 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXV
(Invalidity of the '648 Patent)

283. Par incorporates by reference Paragraphs 1 through 282 of its Counterclaims as if fully set forth herein.

284. The claims of the '648 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et*

seq.

285. A definite and concrete, real and substantial, justiciable controversy exists between Par and Takeda concerning the validity of the '648 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

286. A judicial declaration that the '648 patent is invalid is warranted.

COUNTERCLAIM COUNT XXXVI
(Exceptional Case)

287. Par incorporates by reference Paragraphs 1 through 286 of its Counterclaims as if fully set forth herein.

288. This is an exceptional case under 35 U.S.C. § 285.

289. Par should receive an award of its attorneys' fees, costs, and expenses in this action.

PRAYER FOR RELIEF

WHEREFORE, Par requests the following relief:

a) Dismissing the Amended Complaint with prejudice and denying each request for relief made by Takeda;

b) Declaring all claims of the Gout Patents and FMF Patents invalid;

c) Declaring Par's ANDA Product will not contribute to the infringement of any claim of the Gout Patents;

d) Declaring that Par's ANDA Product will not infringe any claims of the FMF Patents;

d) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par its attorneys' fees, costs, and expenses in this action; and

e) Awarding Par such other and further relief as the Court deems just and proper.

/s/ Steven J. Fineman
Steven J. Fineman (#4025)
Katharine C. Lester (#5629)
RICHARDS, LAYTON & FINGER P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651–7700
fineman@rlf.com
lester@rlf.com

OF COUNSEL:

Richard J. Berman
Janine A. Carlan
Aziz Burgy
Bradford C. Frese
Stephen Yang
ARENT FOX LLP
1717 K Street NW
Washington, DC 20036
(202) 857-6000

Attorneys for Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.

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